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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,426	11/02/2001	Hiroshi Handa	47115 CIP DIV2 (71526)	4196

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EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,426

Applicant(s)

Hunda Inf

Examiner

R/alt

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/2/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 19 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 19 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☒ received in Application No. (Series Code/Serial Number) 08/295,927
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 Filed 2/25/02
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The preliminary amendment of 11/2/01 canceled claims 1-18 and added new claim 19.

Claim 19 is examined on the merits, which is the only claim in the application.

5 ***Specification***

The disclosure is objected to because of the following informalities: the specification at page 25, line 29 discloses SEQ IN NO:4 as containing 318 amino acids. However, the information for SEQ IN NO:4 on page 60 shows 319 amino acids.

10 Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20 Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was
25 filed, had possession of the claimed invention.

The specification fails to disclose a protein comprising an amino acid sequence represented by SEQ ID NO:2 "in which one or more amino

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acids are deleted, added or substituted". Adequate support is not found in the specification for sequence 2 having "deleted, added or substituted" amino acids. No specific amino sequence having an SEQ ID NO is disclosed resulting from modifying sequence 2 as claimed.

Claim Rejections - 35 USC § 112

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for amino acid sequence SEQ ID NO:2 being contained by a protein that binds to 3-[5-(2,3-dimethoxy-6-methyl-1,4-benzoquinolinyl)]-2-nonyl-2-propionic acid (E3330), does not reasonably provide enablement for sequence 2 being contained by any protein and for sequence 2 having one or more amino acids deleted, added or substituted. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification fails to describe how to obtain a protein other than one that binds to E3330 as comprising the claimed amino acid sequence. Furthermore, there is no enabling description of deleting, adding or substituting one or more amino acids in the claimed amino acid sequence 2. No specific amino acid sequence having an SEQ ID NO is described that resulted from modifying sequence 2 by deleting, adding or substituting amino acids.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is confusing by reciting "in which one or more amino acids are deleted, added or substituted". It is uncertain how this limitation modifies and defines sequence 2 and/or the protein containing the sequence. The specification does not use and define the claimed language. Is this limitation claiming variations of amino acid SEQ ID NO:2 resulting from deleting, adding or substituting amino acids in sequence 2, or does the limitation have some other relationship to sequence 2 and/or the protein. If variations of sequence 2 are intended, it is uncertain as to what these variations would be since the specification describes only sequence 2 (page 25, line 21), and does not describe SEQ ID NOS for sequences resulting from deleting, adding or substituting amino acids in sequence 2.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matthews et al (5,717,058).

The claim is drawn to a protein comprising an amino acid sequence represented by SEQ ID NO:2 in which one or more amino acids are deleted, added or substituted.

Matthews et al disclose (col 8, lines 37-39) nuclear factor Ref-1.

Ref-1 is a protein comprising the claimed amino acid sequence 2. See the present specification (page 25, lines 17-30) where sequence 2 is described as being contained by E3330-binding protein identical to Ref-1 protein. Furthermore, attached to the copy of form 1449 is a search by the Scientific and Technical Information Center of the

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Patent Office showing 100% query match with S23550 which document CQ (XP-002144595) on form 1449 describes as being Ref-1 protein.

If claim 19 is intended to claim a variation of amino acid sequence 2 with an amino acid deleted, added or substituted, such
5 deletion, addition or substitution of an amino acid would have been merely a matter of individual preference well within the ordinary skill of the art and obvious in the absence of an unexpected change in function or result.

Claim Rejections - 35 USC § 102

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Claim 19 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kelley et al (6,252,048 B1).

The invention is described above.

15

Protein SEQ ID NO:12 of Kelley et al contains an amino acid sequence identical to amino acid sequence 2 of the present claim.

Attached to the copy of form 1449 is a search by the Scientific and Technical Information Center of the Patent Office showing 100% query match with sequence 12 of U.S. Patent Application 09/542,403
20 that issued as Patent 6,252,048 B1.

If claim 19 is intended to claim a variation of amino acid sequence 2 with an amino acid deleted, added or substituted, such deletion, addition or substitution of an amino acid would have been merely a matter of individual preference well within the ordinary

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skill of the art and obvious in the absence of an unexpected change in function or result.

The parent applications cannot provide priority to antedate Kelley et al since the parent applications are not enabled for a protein as claimed, i.e. any protein comprising amino acid sequence 2 having any amino acid deletions, additions or substitutions. The first disclosure of such a protein occurs in instant claim 19.

Claim Rejections - 35 USC § 102

Claim 19 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(b) as obvious over Robson et al (XP002144594) (document CP on form 1449).

The claimed invention is described above.

Robson et al disclose a protein identified as APE1-Human also known as REF-1 protein.

Attached to the copy of form 1449 is a search by the Scientific and Technical Information Center of the Patent Office showing 100% query match with the protein of Robson et al.

If claim 19 is intended to claim a variation of amino acid sequence 2 with an amino acid deleted, added or substituted, such deletion, addition or substitution of an amino acid would have been merely a matter of individual preference well within the ordinary skill of the art and obvious in the absence of an unexpected change in function or result.

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Claim Rejections - 35 USC § 102

Claim 19 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(b) as obvious over Xanthoudakis et al (XP002144595) (document CQ on form 1449).

5 The claimed invention is described above.

Xanthoudakis et al disclose protein S23550 also known as ref-1 protein.

As stated above, the search by the patent office attached to the copy of form 1449 shows 100% query match with the protein of Xanthoudakis et al.

If claim 19 is intended to claim a variation of amino acid sequence 2 with an amino acid deleted, added or substituted, such deletion, addition or substitution of an amino acid would have been merely a matter of individual preference well within the ordinary skill of the art and obvious in the absence of an unexpected change in function or result.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5 Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,986,072. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent disclose a microsphere and process
10 for isolating a substance that binds to E3330 wherein E3330 is coupled to polymer via a spacer, and the substance that binds to E3330 can be a protein having SEQ IN NO:4 in which one or more amino acids are deleted, added or substituted (claim 8). Sequence 4 is the sequence for protein Ref-1, and a protein presently claimed would have been
15 obvious from claims of the patent.

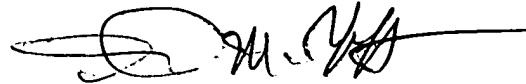
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is 703-308-0196.

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A handwritten signature in black ink, appearing to read 'D. M. Naff', with a long horizontal line extending to the right.

David M. Naff
Primary Examiner
Art Unit 1651

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DMN
9/24/03